

JC04 PCT/PTO 08 JUL 2005

# 4

Docket No.: 67440-A-PCT-US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Mohammad R. Marzabadi, et al.

Confirmation No.: 2867

Application No.: 10/518,939

Group Art Unit: Not Yet Assigned

International Filing Date: July 3, 2003

Examiner: Not Yet Assigned

International Application No.: PCT/US2003/021348

For: SPIROCYCLIC PIPERIDINES AS MCH1 ANTAGONISTS AND USES  
THEREOF

Lundbeck Research USA, Inc.  
215 College Road  
Paramus, New Jersey 07652

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

RECEIVED

29 DEC 2005

Legal Staff  
International Division

**COMMUNICATION IN RESPONSE TO NOTIFICATION OF  
MISSING REQUIREMENTS UNDER 35 U.S.C. §371 IN THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)**

Dear Sir:

This Communication is submitted in response to the Notification of Missing Requirements Under 35 U.S.C. §371 in the United States Designated/Elected Office (DO/EO/US) issued May 20, 2005 by the U.S. Patent and Trademark Office in connection with the above-identified application. A response to the May 20, 2005 Notification of Missing Requirements is due July 20, 2005. Accordingly, this Communication is being timely filed.

The Notice, a copy of which is enclosed herewith, indicates that the oath or declaration does not comply with 37 C.F.R. 1.497(a) and (b) in that it is not executed in accordance with either 37 C.F.R. §1.66 or 37 C.F.R. §1.68. The Notice further indicates that the second inventor's name on the declaration does not correspond with the name on the published international application. The Notice further indicates

03/21/2006 CSN001 00000006 503201 10518939  
Sale Ref: 00000006 DHH: 503201 10518939  
21 FEB 2006 14:22 403 00 00

that the seventh inventor does not appear on the published international application and that an IB Form 306 was not submitted that indicates the change.

37 CFR §1.68 states:

Any document to be filed in the Patent and Trademark Office and which is required by any law, rule, or other regulation to be under oath may be subscribed to by a written declaration. Such declaration may be used in lieu of the oath otherwise required, if, and only if, the declarant is on the same document, warned that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application or any patent issuing thereon. The declarant must set forth in the body of the declaration that all statements made of the declarant's own knowledge are true and that all statements made on information and belief are believed to be true.

In response to the allegation that the December 17, 2004 Declaration was not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68, applicants note that the statements set forth in 37 CFR §1.68 and recited above are included on page 2 of the December 17, 2004 Declaration. Page 2 of the December 17, 2004 Declaration states:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Accordingly, applicants maintain that the December 17, 2004 Declaration was executed in accordance with 37 CFR 1.68.

In response to the allegation that the December 17, 2004 Declaration does not comply with 37 CFR 1.497(a) and 1.497(b) because the second inventor's name on the

declaration does not correspond with the name on the published international application, applicants enclose herewith the Declaration of Yu Jiang. In his Declaration Dr. Jiang states that an unsigned PCT Request Form was filed at the United States Receiving Office when the PCT International Application was filed on July 3, 2003. The unsigned PCT Request Form incorrectly states his legal name as "Allen" Jiang. "Allen Jiang" is also identified as the second inventor on the published PCT Application, WO 2004/004714. Dr. Jiang further states that a signed PCT Request Form was filed at the United States Receiving Office on September 10, 2003 in response to August 18, 2003 Invitation to Correct Defects in the International Application and that his name is correctly identified on the signed PCT Request Form as "Yu Jiang". Dr. Jiang further declares that although his legal name is "Yu Jiang", in social situations, he goes by both his legal name and his nickname of 'Allen'.

In response to the allegation that the December 17, 2004 Declaration does not comply with 37 CFR 1.497(a) and 1.497(b) because the seventh inventor, Kim Andersen, does not appear on the published application, Applicants enclose herewith a copy of an Form PCT/IB/306 which was issued by the International Bureau of WIPO on February 14, 2005. Form PCT/IB/306 states that Kim Andersen is added as an applicant to PCT/US2003/021348 for the US only.

- 37 CFR §1.41(a)(4) states:

The inventorship of an international application entering the national stage under 35 U.S.C. 371 is that inventorship set forth in the international application, which includes any change effected under PCT Rule 92bis.

Accordingly, applicants maintain that Kim Andersen is a co-inventor of the subject application and therefore the December 17, 2004 Declaration does comply with 37 CFR 1.497(a) and 1.497(b).

The Notification of Missing Requirements issued May 20, 2005 indicates that a fee of \$130.00 for providing the oath or declaration later than 30 months from the priority date was needed. Applicants believe that no fee is deemed necessary in connection with the filing of this Communication since the executed declaration was timely filed on December 17, 2004. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 503201.

Respectfully submitted,



Stephen G. Kalinchak, Esq.  
Registration No. 38,747  
Lundbeck Research USA, Inc.  
215 College Road  
Paramus, New Jersey 07652  
Phone: (201) 350-0540  
Fax: (201) 986-9106

07/14/2005 ATRAN1 00000057 10518939

01 FC:1617 130.00 DA



Docket No.  
67440-A-PCT-US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: **Mohammad R. Marzabadi, et al.** Group Art Unit: **Not Yet Assigned**

Application No.: **10/518,939**

Examiner: **Not Yet Assigned**

International Application Filing Date: **July 3, 2003**

International Application No.: **PCT/US2003/021348**

For: **SPIROCYCLIC PIPERIDINES AS MCH1 ANTAGONISTS AND USES THEREOF**

Date: **July 6, 2005**

**CERTIFICATE OF MAILING**  
**BY "FIRST CLASS MAIL" (37 C.F.R. § 1.8)**

Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

I hereby certify that the following correspondence:

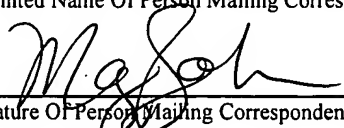
**Communication In Response To Notification of Missing Requirements Under 35 U.S.C. §371 in the United States Designated/Elected Office (DO/EO/US) (4pgs); Copy of May 20, 2005 Notification of Missing Requirement Under 35 U.S.C. §371 in the United States Designated/Elected Office (DO/EO/US) (2pgs); Declaration of Yu Jiang (2pgs); Copy of Form PCT/IB/306 (1pg); and Return Postcard**

is being deposited on **July 6, 2005** with the United States Postal Service as first class mail in an envelope bearing sufficient postage thereon and addressed to:

**Commissioner for Patents**  
**PO Box 1450**  
**Alexandria, Virginia 22313-1450.**

**Mary Johnson**

(Typed Or Printed Name Of Person Mailing Correspondence)

  
(Signature Of Person Mailing Correspondence)



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/518,939	Mohammad R Marzabadi	67440-A-PCT-US

INTERNATIONAL APPLICATION NO.
PCT/US03/21348

45821  
LUNDBECK RESEARCH USA, INC.  
ATTENTION: STEPHEN G. KALINCHAK, LEGAL  
215 COLLEGE ROAD  
PARAMUS, NJ 07652

Received  
Synaptic Pharmaceutical

MAY 25 2005

Legal Department

LA. FILING DATE	PRIORITY DATE
07/03/2003	07/03/2002

CONFIRMATION NO. 2867  
371 FORMALITIES LETTER



\*OC000000016081620\*

Date Mailed: 05/20/2005

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 12/17/2004
- Copy of the International Search Report filed on 12/17/2004
- Copy of IPE Report filed on 12/17/2004
- Oath or Declaration filed on 12/17/2004
- Request for Immediate Examination filed on 12/17/2004
- U.S. Basic National Fees filed on 12/17/2004
- Assignment filed on 12/17/2004
- Priority Documents filed on 12/17/2004
- Specification filed on 12/17/2004
- Claims filed on 12/17/2004
- Abstracts filed on 12/17/2004

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date. The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) in that it:
  - is not executed in accordance with either 37 CFR 1.66 or 37 CFR 1.68.
  - The second inventor's name on the declaration does not correspond with the name on the published international application. In addition, the seventh inventor does not appear on the published international application. I do not have an IB Form 306 indicating any changes.
- \$130 Surcharge for providing the oath or declaration later than 30 months from the priority date (37 CFR 1.492(e)) is required.

**SUMMARY OF FEES DUE:**

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Late oath or declaration Surcharge.

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

WINSTON M ALVARADO

Telephone: (703) 308-9140 EXT 206

**PART 1 - ATTORNEY/APPLICANT COPY**

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/518,939	PCT/US03/21348	67440-A-PCT-US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Mohammad R. Marzabadi, et al.

Confirmation No.: 2867

Application No.: 10/518,939

Group Art Unit: Not Yet Assigned

International Filing Date: July 3, 2003

Examiner: Not Yet Assigned

International Application No.: PCT/US2003/021348

For: SPIROCYCLIC PIPERIDINES AS MCH1 ANTAGONISTS AND USES THEREOF

Lundbeck Research USA, Inc.  
215 College Road  
Paramus, New Jersey 07652

Commissioner for Patents  
P.O. Box 1450  
Washington, D.C. 22313-1450

Sir:

**DECLARATION OF YU JIANG**

I, Yu Jiang, Ph.D., hereby declare as follows:

1. An unsigned PCT Request Form (PCT/RO/101) was filed in connection with PCT International Application No. PCT/US2003/021348 at the United States Receiving Office (RO/US) on July 3, 2003.
2. My legal name was incorrectly identified on the unsigned PCT Request Form as 'Allen' Jiang.
3. An Invitation to Correct Defects in the International Application (PCT/RO/106) was issued by the United States Receiving Office on August 18, 2003. Annex A of the Invitation stated that PCT International Application No. PCT/US2003/021348 was objected to because the PCT Request Form was not signed by all of the applicants.
4. On September 10, 2003 a Communication In Response To August 18, 2003 Invitation to Correct Defects in the International Application (hereinafter, "Communication") was

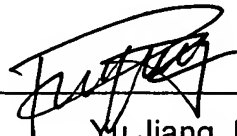


filed with the United States Receiving Office. The Communication included as Exhibit B thereto a signed PCT Request Form. My legal name is correctly identified on the signed PCT Request Form as Yu Jiang.

5. On September 10, 2003 an executed Assignment was filed for recordation in the U.S. Patent and Trademark Office connection with PCT International Application No. PCT/US2003/021348. My legal name is correctly identified on the Assignment as Yu Jiang.
6. My legal name is incorrectly identified as 'Allen' Jiang on the front page of PCT International Application No. PCT/US2003/021348, published January 15, 2004.
7. On December 9, 2004 I executed a Combined Declaration and Power of Attorney in connection with the national stage filing of PCT/US2003/021348. My legal name is correctly identified on the Combined Declaration and Power of Attorney as Yu Jiang.
8. My legal name is Yu Jiang which I use in connection with all legal and business matters. However, in social situations, I am identified either by my legal name, Yu Jiang, or by my nickname 'Allen'.
9. I hereby declare that all statements made herein are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that any such willful false statements may jeopardize the validity of the application or any patent issued thereon.

07/06/2005

Date



Yu Jiang, Ph.D.



(43) International Publication Date  
15 January 2004 (15.01.2004)

PCT

(10) International Publication Number  
WO 2004/004714 A1

(51) International Patent Classification<sup>7</sup>: A61K 31/438,  
C07D 221/20, 491/10

John [PH/US]; 7427 Boulevard East, Apartment 5, North  
Bergen, NJ 07047 (US). WETZEL, John [US/US]; 16-08  
Well Drive, Fairlawn, NJ 07410 (US).

(21) International Application Number:

PCT/US2003/021348

(74) Agent: WHITE, John, P.; Cooper & Dunham LLP, 1185  
Avenue of the Americas, New York, NY 10036 (US).

(22) International Filing Date: 3 July 2003 (03.07.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
10/189,146 3 July 2002 (03.07.2002) US

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,  
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,  
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,  
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,  
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,  
MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC,  
SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA,  
UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(63) Related by continuation (CON) or continuation-in-part

(CIP) to earlier application:

US 10/189,146 (CIP)  
Filed on 3 July 2002 (03.07.2002)

(84) Designated States (*regional*): ARIPO patent (GH, GM,  
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),  
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),  
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,  
ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,  
SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM,  
GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(71) Applicant (*for all designated States except US*): SYNAP-  
TIC PHARMACEUTICAL CORPORATION [US/US];  
215 College Road, Paramus, NJ 07652 (US).

Published:

- with international search report
- before the expiration of the time limit for amending the  
claims and to be republished in the event of receipt of  
amendments

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): MARZABADI, Mo-  
hammad [US/US]; 153 Woodland Avenue, Ridgewood,  
NJ 07450 (US). JIANG, Allen [CN/US]; 179 Mahattan  
Avenue, Apartment 7B, Jersey City, NJ 07370 (US).  
LU, Kai [CN/US]; 67A, Glenwood Avenue, Elmwood  
Park, NJ 07407 (US). CHEN, Chien-An [—/US]; 49-02  
196th Place, Fresh Meadows, NY 11365 (US). DELEON,

For two-letter codes and other abbreviations, refer to the "Guid-  
ance Notes on Codes and Abbreviations" appearing at the begin-  
ning of each regular issue of the PCT Gazette.

(54) Title: SPIROCYCLIC PIPERIDINES AS MCH1 ANTAGONISTS AND USES THEREOF

(57) Abstract: This invention is directed to compounds which are selective antagonists for melanin concentrating hormone-1 (MCH1) receptors. The invention provides a pharmaceutical composition comprising a therapeutically effective amount of the compound of the invention and a pharmaceutically acceptable carrier. This invention provides a pharmaceutical composition made by combining a therapeutically effective amount of the compound of this invention and a pharmaceutically acceptable carrier. This invention further provides a process for making a pharmaceutical composition comprising combining a therapeutically effective amount of the compound of the invention and a pharmaceutically acceptable carrier. This invention also provides a method of reducing the body mass of a subject which comprises administering to the subject an amount of a compound of the invention effective to reduce the body mass of the subject. This invention further provides a method of treating a subject suffering from depression and/or anxiety which comprises administering to the subject an amount of a compound of the invention effective to treat the subject's depression and/or anxiety. This invention further provides a method of treating a subject suffering from a urinary disorder.

20082/200849-  
WO

## PCT

NOTIFICATION OF THE RECORDING  
OF A CHANGE(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

To:

LUDWIG, Peter, S.  
Darby & Darby P.C.  
P.O. Box 5257  
New York, NY 10150-5257  
United States of America

Date of mailing (day/month/year)

14 February 2005 (14.02.2005)

Applicant's or agent's file reference

2200899-WO0

## IMPORTANT NOTIFICATION

International application No.

PCT/US2003/021348

International filing date (day/month/year)

03 July 2003 (03.07.2003)

## 1. The following indications appeared on record concerning:



the applicant



the inventor



the agent



the common representative

Name and Address

ANDERSEN, Kim  
744 Fernwood Ct  
Ridgewood, NJ 07450  
United States of America

State of Nationality

DK

State of Residence

US

Telephone No.

Facsimile No.

Teleprinter No.

## 2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:



the person



the name



the address



the nationality



the residence

Name and Address

ANDERSEN, Kim  
744 Fernwood Ct  
Ridgewood, NJ 07450  
United States of America

State of Nationality

DK

State of Residence

US

Telephone No.

Facsimile No.

Teleprinter No.

## 3. Further observations, if necessary:

The above mentioned person is applicant for the US only.

## 4. A copy of this notification has been sent to:



the receiving Office



the designated Offices concerned



the International Searching Authority



the elected Offices concerned



the International Preliminary Examining Authority



other:

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

Marianne ROUX (Fax 338 9090)

Facsimile No. (41-22) 338.90.90

Telephone No. (41-22) 338 9574